UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION II
290 BROADWAY
NEW YORK, NEW YORK 10007-1866

DATE: June 06, 2019

SUBJECT: Diamond Alkali OU4 - Lower Passaic River Study Area, Baseline Ecological Risk Assessment, Revision 3 Draft, Consideration of Peer Review Handbook, 4th Edition

FROM: Diane Salkie, Remedial Project Manager
Passaic, Hackensack, Newark Bay Remediation Branch

TO: File

The U.S. Environmental Protection Agency (EPA) Region 2 has evaluated the Baseline Ecological Risk Assessment (BERA) report (Windward, 2018) prepared by the potentially responsible parties, under EPA oversight, for the Diamond Alkali Site Operable Unit 4, from here on out referred to as the Lower Passaic River Study Area (LPRSA) in consideration of the EPA's Peer Review Handbook, 4th Edition (EPA, 2015). The LPRSA BERA has been performed in accordance with EPA's guidance, guidelines and policies on risk assessment and builds on a long history of assessments conducted by EPA and potentially responsible parties across the country under the Superfund program. Both the EPA guidance, guidelines and policies and the other risk assessments that served as precedents for the BERA were subject to external peer reviews and public comment.

The first through fourth editions of EPA's Peer Review Handbook (EPA 2015) determines that a peer review may not be necessary if an application of an adequately peer-reviewed work product does not depart significantly from its scientific or technical approach or when the scientific or technical methodologies or information being used are commonly accepted in the field of expertise and have the appropriate documentation to support the commonly held view.

In the second edition of the Peer Review Handbook, and in later editions, the document discusses peer-input during the development of the product. During development of the LPRSA BERA work product, there was extensive interaction between staff including EPA Region 2, the New Jersey Department of Environmental Protection (NJDEP), the United States National Oceanic and Atmospheric Administration, the United States Fish and Wildlife Service and the potentially responsible parties, Cooperating Parties Group. Under these circumstances, including the on-going interaction and evaluation of comments received from all parties, it was determined that a peer-review of the BERA is not necessary.

In addition, at the request of NJDEP, EPA Region 2 had an in-person meeting to discuss the use of two Toxicity Reference Values (TRVs) in the BERA. Attendees at the meeting were EPA Region 2, NJDEP, and the Deputy Branch Chief from EPA's Environmental Response Team in the Office of Land and Emergency Management (OLEM) in Headquarters. During the meeting, the Deputy Branch Chief from OLEM indicated the use of two TRVs is an acceptable path forward for an ecological risk assessment and noted that a peer review on this issue was not needed.

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Conclusions

EPA has determined that the LPRSA BERA is not a work product that would be classified with either of the following designations: Influential Scientific Information (ISI) or Highly Influential Scientific Assessment (HISA). Although designated as Other Scientific or Technical Work Product, consistent with the criteria set forth in Section 3 of the 4th Edition of the Peer Review Handbook and as outlined in the attached EPA Peer Review Decision Summary Document (See Attachment 1) and EPA Peer Review Decision Summary Documentation: Explanation (See Attachment 2), peer review of this work product is not considered necessary. The LPRSA BERA does not establish significant precedent, model, or methodology that would require a peer review.

References

EPA (United States Environmental Protection Agency). 2015. Peer Review Handbook, 4th Edition. Science and Technology Policy Council. EPA/100/B-15/001. October.

Windward (Windward Environmental, LLC). 2018. Lower Passaic River Study Area Baseline Ecological Risk Assessment; Revision 3 Draft. Prepared for: USEPA Region 2 as part of the 17-Mile LPRSA Remedial Investigation/Feasibility Study. October 1, 2018.

Attachment 1

EPA Peer Review Decision Summary Documentation
(from Exhibit 3 on p. 15 of EPA's Peer Review Handbook, 4th Edition)

1. **Work Product Title**: Lower Passaic River Study Area Baseline Ecological Risk Assessment; Revision 3 Draft

2. **Work Product Description**: Baseline Ecological Risk Assessment (BERA) prepared as part of the Lower Passaic River Study Area (LPRSA) remedial investigation/feasibility study (RI/FS) conducted under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly referred to as Superfund.

   The BERA was performed in accordance with EPA's guidance on risk assessment that includes guidance, policies, and guidelines from Superfund and other parts of the Agency. The report builds on a long history of assessments conducted by EPA and potentially responsible parties under EPA oversight, across the country under the Superfund program and meets the goals of the Superfund program for consistency in assessments.

   EPA ecological guidance, guidelines, and procedures that served as the basis for the BERA were developed by EPA and were subject to public comment and external peer review:

   Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments. Interim Final, EPA 540-R-97-006, OSWER 9285.7-25, June 1997.
   Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F. EPA Risk Assessment Forum. 1998.
   Issuance of Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund Sites. OSWER Directive 99285.7-28. 1999.
   Additionally, the sources of ecological toxicity values, and the methods of deriving them were also made available for public comment and external peer review:
   Framework for the Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans, and Biphenyls in Ecological Risk Assessment. EPA/100/R-08-004. EPA Risk Assessment Forum. 2008.
   EPA's Ambient Water Quality Criteria were used for various contaminants (e.g., aldrin/dieldrin, chlordane, DDT, PCBs, mercury, arsenic, cyanide). Database available at: https://www.epa.gov/wqc
   Great Lakes Water Quality Initiative criteria documents for the protection of wildlife were used for various contaminants (e.g., DDT, mercury, 2,3,7,8-TCDD, PCBs). Database available at: https://www.epa.gov/gliclearinghouse .
   EPA's ECOTOXicology database (https://cfpub.epa.gov/ecotox)

   Thus, the BERA does not establish significant precedent, model, or methodology that would require a peer review.

3. **Assistant Administrator (AA)-ship or Region and Originating Office/Division**: EPA Region 2/ Superfund and Emergency Management Division
4. **Decision/Rule/Regulation/Action/Activity That the Work Product Supports**: The forthcoming Record of Decision (ROD) for the LPRSA. Specifically, the BERA supports a decision about whether action is warranted at the LPRSA due to ecological risks and the associated remediation levels that will be documented in an anticipated ROD.

5. **Categorization of Work Product**
   a. ___Influential Scientific Information (ISI)
   b. ___Highly Influential Scientific Assessment (HISA)
   c. _X Other Scientific or Technical Work Product

6. **Rationale for Work Product Categorization and if Peer Review is needed**: Consistent with criteria identified in Section 3.3.2 of the handbook, peer review is not needed. The BERA was performed in accordance with EPA's guidance on risk including Superfund specific guidance such as Ecological Risk Assessment Guidance for Superfund. The assessment builds on a long history of assessments conducted by EPA and by potentially responsible parties under EPA oversight across the country under the Superfund program. Thus, the BERA does not establish significant precedent, model or methodology that would require a peer review.

7. **Peer Review Mechanism(s) to Be Used, If Applicable (check all that apply)**: (If the work product is designated as ISI or a HISA, conduct peer review [unless exempted or deferred]. For other scientific or technical work products, peer review should be conducted if the Decision Maker [DM] determines that it is appropriate. Evaluate and allot sufficient resources, including funds, time and personnel.)
   a. _X_ Peer Review Not Necessary
   b. ___ Internal
   c. ___ External: Submit to Peer-Reviewed Journal
   d. ___ External: Letter Reviews
   e. ___ External: Contractor-Managed Panel
   f. ___ External: Federal Advisory Committee (FAC) (e.g., Science Advisory Board [SAB])
   g. ___ External: Other Panels (e.g., National Academy of Sciences [NAS])

8. **Opportunities for Public Participation (check all that apply)**:
   a. ___ Comment on Charge
   b. ___ Nominate Potential Peer Reviewers
   c. ___ Comment on Potential Peer Reviewers
   d. ___ Comment on Draft Work Product
   e. ___ Comment on Peer Review Mechanism
   f. ___ Oral Presentation to Reviewers

Documentation/Approval of Decision for Peer Review Not Necessary

Peer Review Coordinator (Concurrence) Linda M. Mauel
Linda M. Mauel, EPA Region 2 Peer Review Coordinator
Date 6/6/19

Decision Maker (Approval) _____
Pat Evangelista, Acting Director, Superfund and Emergency Management Division
Date 6/6/19

Note: A peer review has not been deemed necessary. Therefore, a peer review leader has been identified for this project.

Attachment 2

EPA Peer Review Decision Summary Documentation: Explanation (from Exhibit 3, page 16 of EPA's Peer Review Handbook, 4th Edition)

Designate the Work Product Category – Decision Maler (DM) and Peer Review Coordinator (PRC)		
Is Work Product Scientific or Technical (includes economic and social work products)?	3.1.1	Yes, under the category of other scientific or technical work. The BERA was performed in accordance with EPA's guidance on ecological risk assessment. The report builds on a long history of assessments conducted by EPA and potentially responsible parties across the country under the Superfund program and meets the goals of the Superfund program for consistency in assessments. EPA guidance including ERAGS, guidelines including the EPA Risk Assessment Forum's Guidelines for Ecological Risk Assessment, and policy including OSWER Directive 99285.7-28 Ecological Risk Assessment and Risk Management Principles for Superfund Sites. The guidance and guidelines were subject to public comment and external peer review. Additionally, the EPA sources for toxicity values and for toxicity value derivation methodologies were subject to public comment and peer review. Thus, the BERA does not establish significant precedent, model, or methodology that would require a peer review.
If scientific or technical, which designation does the work product best fit:		
ISI: Will have or does have a clear and substantial impact on important public policies or private sector decisions. Decision makers should consider the following factors when determining whether a product is likely to be influential: a. Establishes a significant precedent, model or methodology.	3.2.1	a. This document does not meet the classification of an ISI.
b. Is likely to have an annual effect on the economy of $100 million or more.		b. No
c. Is likely to adversely affect in a material way the economy; a sector		c. No

of the economy; productivity; competition; jobs; the environment; public health or safety; or state, tribal or local governments or communities		
d. Addresses significant controversial issues		d. No
e. Focuses on significant emerging issues		e. No
f. Has significant cross-Agency/interagency implications		f. No
g. Involves a significant investment of Agency resources		g. No
h. Considers an innovative approach for a previously defined problem/process/methodology		h. No
i. Satisfies a statutory or other legal mandate for peer review		i. No
HISA: A scientific assessment (i.e., an evaluation of a body of scientific/technical knowledge that typically synthesizes multiple inputs, data, models and assumptions and/or applies best professional judgment to bridge uncertainties in available information) that meets the following: a. In addition to meeting the criteria for ISI, could have a potential impact of more than $500 million in any year; or	3.2.3	a. No, the BERA would not have a potential impact of more than $500 million in any year.
b. Is novel, controversial or precedent-setting or has significant interagency interest.		b. No.
Other	3.2.5	a. Yes, see 3.1.1 above.